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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,267	12/31/2001	Sidney Pestka	PBLI-P01-010	9576
28120	7590	06/25/2004	EXAMINER	
ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			PRYOR, ALTON NATHANIEL	
			ART UNIT	PAPER NUMBER
			1616	
DATE MAILED: 06/25/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/040,267

Applicant(s)

PESTKA, SIDNEY

Examiner

Alton N. Pryor

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 26-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 26-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's arguments filed 3/15/04 have been fully considered but they are not persuasive. See arguments below.

- I. Rejection of claim 72 under 35 USC 112, 2nd paragraph will not be maintained. Claim 72 has been cancelled.
- II. Rejection of claim 58 under 35 USC 112, 2nd paragraph will be maintained for reason on record and reason as follows. Applicant's specification does not define what is meant by "small organic compound".
- III. Rejection of claims 26-56, 58-71 under 35 USC 102(b) as being anticipated by Tracey will be maintained for reason on record and reason as follows.

Applicant argues that Tracey states that interferon (IFN) is in a polymer solution, which is dispersed into droplets, which are then frozen by to form microparticles. Applicant argues that in Tracey microparticles are formed by freezing, not by precipitation, prior to the exposure to the frozen nonsolvent ethanol. Applicant also argues that Tracey releases the IFN from a required matrix. Applicant points out that no polymeric matrix is used in instant invention. Examiner argues that instant claims are product by process claims. The product claimed (biological active - lyophilate of a polypeptide -IFN) is well known in the art. Therefore, a product by process claim to a lyophilate of a polypeptide as the product is not novel irrespective to how it is made. In order for a product by process claim to be patentable, the product itself must be patentable. In reference to the exclusion of a polymeric matrix from the instant product by process, the instant claims employ "comprising" language. Therefore, the employment of a "polymeric matrix" is not excluded by instant claims.

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IV. Rejection of claims 26-56,58-71 under 35 USC 102(b) as being anticipated by Violanto will be maintained for reason on record and reason as follows.

Applicant argues that Violanto states that biological actives such as steroids or hormones are in a polymer solution, which is dispersed into droplets, which are then frozen by to form microparticles. Applicant argues that in Violanto microparticles are formed by freezing, not by precipitation, prior to the exposure to the frozen nonsolvent isopropanol. Applicant also argues that Violanto releases the hormone or steroid from a required matrix. Applicant points out that no polymeric matrix is used in instant invention. Examiner argues that instant claims are product by process claims. The product claimed (hormone or steroid) is well known in the art. Therefore, a product by process claim to a hormone or steroid as the product is not novel irrespective to how it is made. In order for a product by process claim to be patentable, the product itself must be patentable. In reference to the exclusion of a polymeric matrix from the instant product by process, the instant claims employ "comprising" language. Therefore, the employment of a "polymeric matrix" is not excluded by instant claims.

V. Provisional Statutory Double Patenting Rejection over instant claim 71 is maintained as being anticipated by claim 80 of US Application no. 10193654. Claims 71 and 80 have identical limitations.

VI. Obviousness type Double Patenting Rejection

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26-70 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 45-80 of U.S. Patent No. 10/193,654. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims are to biological molecules; whereas, the claims in 10/193,654 are to lyophilate of a polypeptide which is a species of the biological molecule genus.

VI. Examiner maintains that the elected composition which comprises IFN is not allowable. See art rejections above.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


ALTON N. PRYOR
PRIMARY EXAMINER
Primary Examiner
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